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Filed : December 14, 2000

SEP 20 2006

REMARKS

By way of summary, Claims 1-10, 21, 29-33, 60-71, and 74 are pending in this application. The Office Action dated June 20, 2006, rejected Claims 1-10, 21, 29-33, and 65-71 as being anticipated under 35 U.S.C. § 102(e). By this Amendment, Claim 65 has been amended. By way of the foregoing amendments and following remarks, it is believed that Claims 1-10, 21, 29-33, 65-71, and 74 are patentably distinguished over the cited reference, and Applicants respectfully request allowance of the pending claims.

Allowed Claims

Applicants would like to thank the Examiner for the indication of allowance of Claims 60-64 in the Office Action dated June 20, 2006.

Claim Rejections under 35 U.S.C. § 102(e)

The Office Action rejected Claims 1-10, 21, 29-33, and 65-71 under 35 U.S.C. § 102(e) as being anticipated by PCT Publication No. WO 95/21576 to Kotula et al. Applicants respectfully traverse this rejection because Kotula fails to identically teach every element of the rejected claims. See M.P.E.P § 2131 (in order to anticipate a claim, a prior art reference must identically teach every element of the claim).

The Kotula Publication

The publication describes a medical device for macerating thrombi. The device includes a shaft and housing with a rotor at one end for macerating thrombi and moving fluid through a portion of the shaft. The publication describes one or more ports located in the walls of the shaft or housing for ejecting treated fluid therethrough. In operation, as the rotor is rotated, it will tend to draw fluid, i.e., blood, into the housing in a proximal direction and expel the fluid out through the ports. This fluid then tends to be drawn back into the distal end of the housing and through the rotor again, setting up a re-circulating vortex that repeatedly passes the fluid across the blades. Equiangular orientation of the ports around the circumference of the device can assist with maintaining equal forces exerted by the ejected fluid to keep the device substantially in the center of the vascular channel. Other orientations can be used to facilitate directing the device as it is being advanced through the vasculature.

Appl. No. : 09/737,165
Filed : December 14, 2000

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Independent Claim 1

The Office Action states the "Kotula et al device is clearly capable of having a sensor in electrical communication with an indicator (located within control (102, 150)) for indicating resistance to rotation of either the rotatable element or rotatable cutter (50)." Office Action dated June 20, 2006, pages 2-3. Claim 1 recites, among other things, "a sensor on the device in electrical communication with an indicator for indicating resistance to rotation of either the rotatable element or rotatable cutter." The Office Action's conclusory remarks that the device is *clearly capable* of having the sensor-indicator system disclosed in Claim 1 relies on no specific teaching or suggestion in Kotula, fails to explain how such a sensor would be implemented into the Kotula device, and fails to consider the significant and innovative reconstruction that would be required to modify the Kotula device in order to meet the limitations of Claim 1. As described, the Kotula device is powered by a pressurized air supply that is channeled through a turbine to rotate the shaft 10. There is no mention in the operation of Kotula regarding any sensor, electrical communication, or any indicator for indicating resistance, nor has the Office Action asserted that these limitations are found in Kotula. Applicants respectfully submit that the Kotula reference does not disclose, teach, or suggest any "sensor on the device in electrical communication with an indicator, for indicating resistance to rotation of either the rotatable element or rotatable cutter," as recited in Claim 1.

Therefore, it is respectfully submitted that Kotula does not teach or suggest all the limitations of Claim 1, and withdrawal of the rejection under 35 U.S.C. § 102(e) is respectfully requested.

Independent Claim 21

The Office Action also states, regarding a limitation of Claim 21, "Kotula et al discloses in figures 1-7, . . . an aspiration lumen (at 24) . . . wherein the cross-sectional area of the aspiration lumen (24) is being at least about 35% of the cross-sectional area of the tubular body (20)." Office Action, page 2. However, there is no teaching in Kotula for an aspiration lumen, let alone one that is sized to be "at least 35% of the cross-sectional area of the tubular body." The Office Action fails to identify the specific teaching in support of this rejection, and Applicants were unable to identify any such support. Kotula teaches that the fluid is to be

Appl. No. : 09/737,165
Filed : December 14, 2000

recirculated through the rotor to minimize the size of thrombi in the fluid. The thrombi are reduced in size until it can be released into the blood system. In some embodiments of Kotula, fluid is pumped by a rotor proximally through the device, but this transfer of fluid is accomplished through pumping by the rotor, not by aspiration, or application of a negative pressure source. As stated in the specification, "The generally rearward thrust of the present rotor . . . can be employed to effectively pump fluid rearwardly for disposal outside of the patient's blood without [] requiring any separate aspiration equipment." Page 30.

Moreover, there is no disclosure, teaching, or suggestion in Kotula of incorporating an aspiration lumen that is at least 35% of the cross-sectional area of the tubular body. While some figures illustrate a space between the rotating member and the outer wall, even if this were determined to be an aspiration lumen, there is no disclosure, teaching, or suggestion that it comprises at least 35% of the cross-sectional area of the tubular body. Furthermore, Kotula does not state that the drawings are to scale, and "when the reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing features are of little value." See M.P.E.P. § 2125 (citing *Hockerson-Halberstadt, Inc. v. Avia Group Int'l*, 222 F.3d 951, 956, 55 USPQ2d 1487, 1491 (Fed. Cir. 2000)). Thus, support for the rejection cannot be based solely on the drawings, and Applicants respectfully submit that there is no written support for the rejection.

Applicants respectfully submit that Kotula does not teach or suggest all the limitations of Claim 21, and withdrawal of the rejection under 35 U.S.C. § 102(e) is respectfully requested.

Independent Claim 29

The Office Action also states, regarding Claim 29, "Kotula et al discloses in figures 1-7 . . . an aspiration lumen (at 24) extending through said tubular body (20)." Office Action, page 2. However, as stated above, Applicants respectfully submit that Kotula does not disclose an aspiration channel. Kotula fails to describe any function related to aspiration with respect to the projection 24. Kotula describes that the projection 24 includes a guidewire tracking channel 28 for directing the distal end of the device through the vasculature. There is no disclosure, teaching, or suggestion that the channel 28 associated with the projection 24 is an aspiration channel or usable for such purposes. Furthermore, Claim 29 further recites, among other things,

Appl. No. : 09/737,165
Filed : December 14, 2000

"an axially extending annular aspiration channel." Applicants respectfully submit that Kotula does not disclose, teach, or suggest such an aspiration channel.

It is respectfully submitted that Kotula does not teach or suggest all of the limitations of Claim 29, and withdrawal of the rejection under 35 U.S.C. § 102(e) is respectfully requested.

Independent Claim 65

The Office Action also states, "Kotula et al discloses in figures 1-7 . . . a control or hub (102) disposed on the proximal end of tubular body (20)." Office Action, page 2. Amended Claim 65 recites, in part, an elongated tubular body, "the elongated tubular body defining an aspiration channel . . . a control disposed at the proximal end of the tubular body, the control including a connecting hub, the connecting hub coupling the tubular body to the control such that the tubular body may rotate relative to the control during operation." As discussed above, Kotula, however, fails to teach a device having an aspiration channel, in combination with a hub that permits rotation relative to the control and that is disposed on the proximal end of the tubular body.

Therefore, it is respectfully submitted that Kotula does not teach or suggest all the limitations of Claim 65, and withdrawal of the rejection under 35 U.S.C. § 102(e) is respectfully requested.

Independent Claim 68

The Office Action rejects independent Claim 68 as being anticipated under 35 U.S.C. § 102(e) by Kotula. Applicants respectfully submit that the Office Action fails to identify any teaching or suggestion from Kotula upon which this rejection is based. Claim 68 recites, among other things, a "control having a drive motor, the drive motor transmitting rotation to the cutter through at least a flexible drive shaft, the cutter capable of axial displacement relative to the control during operation." Kotula does not disclose, teach, or suggest a cutter that is capable of axial displacement with respect to a control during operation. In contrast, the cutter of Kotula has a specific position between the distal end of the shaft and the port. If the cutter is advanced out the distal end of the shaft or is withdrawn proximally beyond the port, the device may not perform the intended function. Furthermore the proximal end of the shaft 10 is fixed within a tubular drive coupling 180. There is no suggestion that the tubular drive coupling 180 is capable of axial movement. Thus, Applicants respectfully submit that Kotula fails to disclose, teach, or

Appl. No. : 09/737,165
Filed : December 14, 2000

suggest a device in which the cutter is capable of axial displacement relative to a control and that the reference does not anticipate Claim 68 under 35 U.S.C. § 102(e).

Therefore, it is respectfully submitted that Kotula does not teach or suggest all the limitations of Claim 68, and withdrawal of the rejection under 35 U.S.C. § 102(e) is respectfully requested.

Dependent Claims 2-10, 30-33, 66-67, 69-71, and 74

Claims 2-10, 30-33, 66-67, 69-71, and 74 which depend from Claims 1, 29, 65, and 68, are believed to be patentable for the same reasons articulated above with respect to Claims 1, 29, 65, and 68, and because of the additional unique features recited therein. Accordingly, it is respectfully submitted that Kotula does not teach or suggest all the limitations of these claims or the independent claims from which these claims depend, and withdrawal of the rejection under 35 U.S.C. § 102(e) is respectfully requested.

CONCLUSION

Applicants have made a good faith effort to respond to the outstanding Office Action. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is cordially invited to contact Applicants' attorney, at the telephone number below, to resolve any such issue promptly.

Applicants respectfully submit that the claims are in condition for allowance. Furthermore, any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used. Any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicants respectfully traverse each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Although changes to the claims have been made, no acquiescence or estoppel is or should be implied thereby; such amendments are made only to expedite prosecution of the present application and are without prejudice to the presentation or assertion, in the future, of claims relating to the same or similar subject matter.

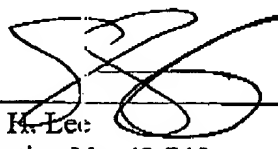
Appl. No. : 09/737,165
Filed : December 14, 2000

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 1-1410.

Respectfully submitted,

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